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IMMULITE 2000/XPi 3gAllergy Specific IgE

Honeybee *(Apis mellifera)* venom component: phospholipase A2, rApi m 1 (A45L2)

Allergen Background

Phospholipase A2 is a major allergen component of honeybee venom *(Apis mellifera)*. IgE antibodies specific to phospholipase A2 bind to recombinant Api m 1 (rApi m 1) and show increased test specificity due to the lack of carbohydrate determinants (CCDs) in the recombinant protein. Various studies have shown that the sensitivity of the recombinant rApi m 1 is up to 80% in patients with honeybee venom allergy and positive skin tests. Cross-reactivity is known to occur between honeybee and bumblebee phospholipase A2 because of similar structural identity. Honeybee venom allergy may cause life-threatening or even fatal systemic allergic reactions. The most common symptoms to honeybee stings are IgE-mediated local reactions and systemic anaphylactic reactions.[1-9]

Biochemical Characteristics

Amino acid sequence of honeybee venom, Api m 1 was cloned and expressed using Sf9 insect cells infected by a recombinant baculovirus.

Clinical Performance

Clinical performance of the rApi m 1-specific allergen was demonstrated in comparison to the native honeybee venom extract (I1). A total of 57 samples were tested with A45 and I1. The results were obtained using the IMMULITE® 2000 3gAllergy™ Specific IgE assay. Overall, positive, and negative agreements are presented to the right.

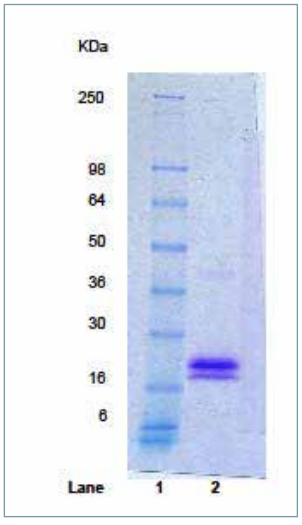

Figure 1.
Coomassie Blue stained gel of rApi m 1, doublet of ~18 kDa and ~22 kDa.

Allergen: rApi m 1
IMMULITE 2000
I1 (Reference Method)

A45 (Test Method)	Positive	Negative	
	29	0	Positive
	2	26	Negative
	Positive	Negative	

N=57

Overall percent agreement: 97% (55/57)
Positive percent agreement: 94% (29/31)
Negative percent agreement: 100% (26/26)

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IMMULITE 2000/XPi 3gAllergy Specific IgE Product Information Sheet

Analytical Performance

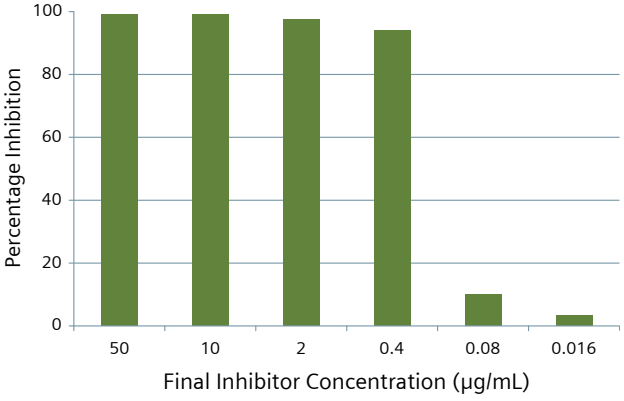
Precision: The average repeatability and within-lab precision using three samples and three lots of rApi m 1 allergen was 4.06% and 5.18%, respectively.

Linearity: Two positive samples were diluted with low sample in increments of 12.5% and tested using three allergen lots. The undiluted (neat) and the diluted samples were assayed in three replicates and the observed value was reported based in the average of the three replicates. Comparisons of the observed to the expected values were used to demonstrate linearity at concentrations within the assay limits.

Regression Equation	Slope 95% CI	R^2
y = 0.98x + 0.04	0.94 – 1.06	0.998

Identity Testing

Identity of rApi m 1 allergen was verified through competitive inhibition testing using a single serum sample. A negative sample was used to measure the background response. The percentage inhibitions are represented in the graph below showing correlation to increasing inhibitor concentrations.



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